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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Docket No. CDC-2015-0016

Proposed Revised Vaccine Information Materials for Seasonal Influenza Vaccines

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. 300aa-26), the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) develops vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. HHS/CDC seeks written comment on the proposed updated vaccine information

statements for inactivated and live attenuated influenza vaccines.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0016, by any of the following methods:

- Federal eRulemaking Portal:
<http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Written comments should be addressed to Suzanne Johnson-DeLeon (msj1@cdc.gov), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A-19, 1600 Clifton Road, NE, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and docket number. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Skip Wolfe (crw4@cdc.gov),
National Center for Immunization and Respiratory Diseases,
Centers for Disease Control and Prevention, Mailstop A-19,
1600 Clifton Road, NE., Atlanta, Georgia 30329.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine
Injury Act of 1986 (Pub. L. 99-660), as amended by section
708 of Public Law 103-183, added section 2126 to the Public
Health Service Act. Section 2126, codified at 42 U.S.C.
300aa-26, requires the Secretary of Health and Human
Services to develop and disseminate vaccine information
materials for distribution by all health care providers in
the United States to any patient (or to the parent or legal
representative in the case of a child) receiving vaccines
covered under the National Vaccine Injury Compensation
Program (VICP).

Development and revision of the vaccine information
materials, also known as Vaccine Information Statements
(VIS), have been delegated by the Secretary to the Centers
for Disease Control and Prevention (CDC). Section 2126
requires that the materials be developed, or revised, after
notice to the public, with a 60-day comment period, and in

consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the

relevant vaccine information materials prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and seasonal influenza vaccines. Instructions for use of the vaccine information materials are found on the CDC Web site at: <http://www.cdc.gov/vaccines/hcp/vis/index.html>.

HHS/CDC is proposing updated versions of the inactivated and live attenuated seasonal influenza vaccine information statements.

The vaccine information materials referenced in this notice are being developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and health care provider groups.

We invite written comment on the proposed vaccine information materials entitled "Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know" and

"Influenza (Flu) Vaccine (Live, Intranasal): What you need to know." Copies of the proposed vaccine information materials are available at <http://www.regulations.gov> (see Docket Number CDC-2015-0016). Comments submitted will be considered in finalizing these materials. When the final materials are published in the Federal Register, the notice will include an effective date for their mandatory use.

Dated: May 14, 2015.

Ron A. Otten,

Acting Deputy Associate Director for Science
Centers for Disease Control and Prevention

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